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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,225	05/04/2001	Kenichiro Shiroyama	Q64175	6389

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EXAMINER
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CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/848,225

Applicant(s)

SHIROYAMA ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of amendment, declaration and remarks dated 4-13-06 is acknowledged.

New claims 15-20 are added. Claims 7 and 12-20 are pending in the instant application.

The following is a new rejection:

#### ***Claim Rejections - 35 USC § 103***

Claims 7 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,294,444 in view of US 5,641,495 to Jokura et al (Jokura).

Nakamura teaches a transparent or semi-transparent cosmetic composition comprising an amphipathic lipid, nonionic surfactant, ionic surfactant and an aqueous medium (abstract, col. 2, lines 1-18). The amphipathic lipids of the Nakamura includes ceramides such as those described by formula I. Nakamura teaches the non-ionic surfactant of instant claim 13 (col. 3, lines 1-5 & tables 2 and 3), cholesterol and fatty acids (table 2). The amounts of ceramides, non-ionic surfactants, fatty acids and cholesterol in the composition taught by Nakamura are within the instant claimed ratios (table 2). With respect to the claimed method step of mixing lipid composition while heating at 80 -120 degrees C and heating water at 80 to 100 degrees C, Nakamura teaches that the components of table 3 were mixed and melted at a temperature of 85-90 degrees C (within the heating temperature of instant claims), followed by addition of hot water (Col. 4, lines 51-55). While Nakamura fails to state the specific temperature of water, absent evidence to the contrary, the term "hot water" includes boiling water,

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which is 100 degrees C or water as hot as 80 C. Nakamura also teaches that the compositions do not irritate the skin, as claimed (col. 1, lines 65-68).

Nakamura teaches ceramides, glycerocermides and ceramide derivatives, but does not teach the ceramides having the structural formula of instant claims.

Jokura teaches a skin cosmetic composition that is less irritating, comprising a ceramides, a dicarboxylic acid and a salt of dicarboxylic acid. Jokura teaches that the composition can include ceramides as well as pseudoceramides, represented by formula 1 and 2, respectively (col. 2, lines 7-30). In particular, formula 2 of Jokura meets the description of ceramides formula of Nakamura. Jokura also teaches linear or branched, saturated or unsaturated ceramides such as N-oleoylsphingosine or N-(12-hydroxyoctadecanoyl sphingosine or N-(16-hydroxyhexadecanoyl) sphingosine (col. 2, lines 40-65 and col. 3, lines 1-10), which meet the claim requirement of natural ceramides (claim 15).

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include ceramides (of Jokura) in the composition of Nakamura to prepare a skin cosmetic composition that is transparent as well as less irritating because Jokura recognizes ceramides as well as pseudoceramides as equivalent in their skin excellent moisturizing effect as well as their low skin irritation. Thus, a skilled artisan would have expected to achieve a transparent skin moisturizing composition that is less irritating to the skin.

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Claims 7 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,294,444 in view of US 6,355,232 to Kaneko et al (Kaneko).

The teachings of Nakamura have been described above. Nakamura fails to teach the claimed optically active compounds.

Kaneko teach skin protective compositions comprising erythro (2S, 3R) type of ceramides having the structural formula I –VI (col. 2, lines 15 through col. 3, lines 57). In particular, the ceramides of structural formula I meets the claimed structure II of claim 15. Kaneko also suggests a combination of amphipathic surfactants such as fatty acids, fatty alcohols etc., and cholesterol or a phytosterol, in the composition (col. 3, lines 58 through col. 4, lines 28). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to replace the ceramides of Nakamura, with the optically active ceramides of Kaneko because Kaneko teaches that the optically active ceramides exert remarkable water-barrier functions in skin protection compositions, as opposed to the racemates and significantly higher water holding capacity than racemates and pseudoceramides (col. 1, lines 59-67 and col. 8, lines 10-15). Thus, a skilled artisan would have expected that the ceramides of Kaneko to function better than the ceramides or pseudoceramides of Nakamura. While Kaneko fails to teach the specific ceramides of claims 18-20, in the absence of establishing an unexpected result with respect to the specific active ceramides taught by Kaneko, one of an ordinary skill in the art at the time of the instant invention was made would understand from the teachings of Kaneko that the 2S, 3R type of ceramides (optically active) are significantly more efficient in their skin moisturizing effect than the racemates

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and pseudoceramides because Kaneko teaches that the water restraining capacity of optically active ceramides is higher than the other ceramides (col. 8, lines 18-56).

### ***Response to Arguments***

Applicant's arguments filed 4-13-06 have been fully considered but they are not persuasive.

Applicants' arguments with respect to the rejection of claims 7 and 12-14 as being unpatentable under 35 USC 103(a) over Cannell or Cannell in view of Cauwet or Cauwet in view of Cannell have been considered. However, the arguments are moot because the rejection has been withdrawn.

### **DECLARATION**

The Declaration under 37 CFR 1.132 submitted by Kenichiro Shiroyama (dated 4-5-06) and applicants' arguments in view of the declaration have been considered but not found persuasive. The declaration presents Tables 1-3, in which the compositions in each of the tables are prepared under the same conditions i.e., heating the lipid components to 80 -120 degrees C and separately heating water 80-100 degrees C and mixing the two. While the declaration states that the examples tested establish the criticality of the claimed temperature for heating the carrier components in order to provide an efficient carrier for lipophilic components such as ceramides, all the examples described in the declaration have been tested or prepared only at the claimed temperature conditions. Control samples, where the compositions have been prepared

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outside the claimed temperature conditions have not been tested. Therefore, in the absence of appropriate controls, the results presented do not establish the criticality of the temperatures claimed.

On page 6 of the declaration, it is stated that the composition of comparative example 2 (containing no ceramides) showed white turbidity whereas clear aqueous compositions were obtained in application example 1, which is the same as the composition of comparative example 2, except for ceramides incorporated therein. However, example 1 and comparative example 2 differ in their components, not just for ceramides, but also in the presence or absence of sodium POE (4) lauryl ether phosphate, butylene glycol, cholesterol and in the amounts of isostearic acid, POE (60) hydrogenated castor oil. Thus, it can be concluded that the absence of ceramides is not the only difference that results in a clear, aqueous solution. The presence of turbidity in comparative example 2 could be attributed to the presence of sodium POE (4) lauryl ether phosphate, butylenes glycol, and cholesterol and in the amounts of isostearic acid; POE (60) hydrogenated castor oil, in addition to the lack of ceramides.

Further, applicants state that the each of the compositions of examples 1 to 8 had a pH near neutrality resulting in skin friendly and non-irritating compositions. However, a careful review of the components of the compositions reveal that the pH of the composition is a result of the components added and has not been adjusted to a desired pH after adding the components. Given the fact that the compositions (instant and comparative) are different in their components (as explained in the previous paragraph), one cannot attribute the non-irritating nature to the clarity of the composition

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or the presence of ceramides that result in a high or low pH of the compositions. Instead, the components included in the composition cause the resulting pH of the compositions to be near neutral or alkaline. Examiner notes that the pH of the compositions has not been adjusted to the neutrality or alkalinity and instead measured after preparing the composition (page 2, lines immediately under the heading Experimental Results). Finally, it is well established that alkaline pH is irritating to skin whereas neutral pH is skin-friendly and applicants have not shown any correlation between the optical clarity, presence of ceramides, pH and absence of skin irritation.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615

June 22, 2006